



contacts with the forum in assessing the reasonableness and fairness of conferring jurisdiction on Michigan. We conclude, therefore, that it is not unconstitutional for Michigan to consider Spoon's total contacts with the forum in asserting *in personam* jurisdiction over him.

Accordingly, the decision of the District Court finding personal jurisdiction over defendant Spoon is affirmed. That part of the opinion awarding summary judgment to plaintiff for \$14,200.00 is vacated. The cause is remanded to the District Court to permit a determination of the amount actually paid by Lionel Spoon and for entry of judgment in either that amount or in the amount of \$14,200.00, whichever is lesser.

IT IS SO ORDERED.



**The UPJOHN MANUFACTURING COMPANY and The Upjohn Company,**  
Plaintiffs-Appellants,

v.

**Richard S. SCHWEIKER, Secretary, et al.,**  
Defendants-Appellees.

No. 81-1517.

United States Court of Appeals,  
Sixth Circuit.

Argued April 19, 1982.

Decided June 29, 1982.

As Amended July 23, 1982.

American drug manufacturer which had filed pioneer new drug applications for a drug filed action challenging Food and Drug Administration's approval of a new drug application to a British manufacturer and distributor of the same drug. The United States District Court for the Western District of Michigan, 520 F.Supp. 58, Benjamin F. Gibson, J., granted defendant's

motion for summary judgment, and plaintiff appealed. The Court of Appeals, Harry Phillips, Senior Circuit Judge, held that: (1) fact-finding procedures employed by FDA were adequate; (2) district court did not err in refusing to go outside administrative record; (3) there is no evidence that FDA acted arbitrarily or capriciously or abused its discretion or relied upon American manufacturer's trade secret data in approving the application; and (4) FDA's approval of British drug manufacturer's duplicate new drug application would not be reversed on ground that FDA applied different standards in approving that application and a pioneer new drug application filed by American manufacturer.

Affirmed.

# **1. Administrative Law and Procedure** ⌘744

When de novo review of agency action is not expressly required by statute, it is the exception rather than the rule.

## **2. Drugs and Narcotics** ⌘10

The fact-finding procedures employed by Food and Drug Administration in approving British drug manufacturer's new drug application and rejecting American drug manufacturer's petition urging denial of the application was adequate, since FDA followed applicable statutory and regulatory criteria for approving the application, and engaged in informal fact-finding procedures to gather evidence concerning the safety and effectiveness of the drug. Federal Food, Drug, and Cosmetic Act, § 505(d), 21 U.S.C.A. § 355(d).

## **3. Drugs and Narcotics** ⌘10

In action challenging Food and Drug Administration's approval of new drug application, district court did not err in refusing to go outside the administrative record, since FDA stated in detail the grounds for its decision and the essential facts upon which the decision was based.

## **4. Drugs and Narcotics** ⌘10

In action challenging Food and Drug Administration's approval of a new drug

application, there was no evidence that FDA acted arbitrarily or capriciously or abused its discretion, and no evidence that FDA relied upon protester's trade secret data in approving the application.

#### 5. Drugs and Narcotics ⇐9

Food and Drug Administration's approval of British drug manufacturer's duplicate new drug application would not be reversed on ground that FDA applied different standards in approving that application and a pioneer new drug application filed by American manufacturer, since manufacturers were required to meet same statutory criteria in support of their applications, and although there was a difference in the types of information each was required to submit, that disparity and treatment was inherent in FDA's "paper new drug application" policy which establishes a difference in position of party submitting a pioneer new drug application and a party submitting a duplicate new drug application.

#### 6. Drugs and Narcotics ⇐9

The Federal Food, Drug and Cosmetic Act and underlying regulations governing approval of marketing of new drugs were not intended to provide patent-like protection for a seller who has gained approval of a pioneer new drug application. Federal Food, Drug, and Cosmetic Act, § 505(a), (b)(1), 21 U.S.C.A. § 355(a), (b)(1).

James G. Vantine, Jr., Brown, Colman & DeMent, Kalamazoo, Mich., Gerard Thomas, The Upjohn Company, Kalamazoo, Mich., Richard F. Kingham, Washington, D. C., for plaintiffs-appellants.

Robert C. Greene, U. S. Atty., Grand Rapids, Mich., Gerald C. Kell, Consumer Affairs Section Antitrust Division Dept. of Justice, Washington, D. C., Norman Bristol, Howard & Howard, Kalamazoo, Mich., Stanley L. Temko, Herbert Dym, Covington & Burling, Washington, D. C., Jeffrey B. Springer, Acting Chief Counsel, Jeffrey N. Gibbs, Rockville, Md., Robert B. Nicholson, James H. Laskey, Dept. of Justice, Washington, D. C., James Johnstone, Washington, D. C., Robert Pugh, Sr., Shreveport, for defendants-appellees.

Before EDWARDS, Chief Judge, CON-TIE, Circuit Judge, and PHILLIPS, Senior Circuit Judge.

PHILLIPS, Senior Circuit Judge.

This appeal grew out of Food and Drug Administration (FDA) approval of a new drug application filed by a competitor of appellants Upjohn, Boots Pharmaceuticals, Inc. (Boots). In the new drug application, Boots sought permission to manufacture and distribute the drug ibuprofen under the trademark, "Rufen."

FDA had approved a new drug application submitted by Upjohn for ibuprofen in 1974. Upjohn had developed a substantial market for this drug under the name "Motrin." This drug is prescribed for relief of osteoarthritis, rheumatoid arthritis and mild to moderate pain.

Upjohn filed the present suit against the Secretary of Health and Human Services and the Commissioner of Food and Drugs, appellees, challenging the approval of Boots' application as unlawful and seeking a declaratory judgment and injunctive relief. District Judge Benjamin F. Gibson granted the motion of defendants for summary judgment. Upjohn appeals. We affirm. Reference is made to the comprehensive opinion of Judge Gibson for a recitation of pertinent facts. *Upjohn Manufacturing Co. v. Schweiker*, 520 F.Supp. 58 (W.D.Mich.1981).

#### I

In 1961, a British corporation, the Boots Company, Ltd. (the parent of Boots Pharmaceuticals) synthesized the chemical ibuprofen and obtained patents for it in 45 countries, including the United States. In 1969, Upjohn purchased a nonexclusive license from the Boots Company, Ltd., to sell ibuprofen in the Western Hemisphere.

Before Upjohn could market ibuprofen in the United States, it was required to obtain FDA approval of a new drug application. 21 U.S.C. § 355(a). A new drug application

must show with "full reports and investigations" that the drug is "safe . . . and effective." 21 U.S.C. § 355(b)(1).

Upjohn states that it spent approximately \$5 million in gaining FDA approval in 1974 to market ibuprofen for relief of the symptoms of osteoarthritis and rheumatoid arthritis. Later, Upjohn avers, it spent an additional \$1 million and gained FDA approval to market ibuprofen tablets for relief of mild to moderate pain. As stated above, Upjohn markets the drug under the name "Motrin."

Upjohn's investment proved to be profitable. Motrin is the leading drug in the arthritis prescription market. In 1981 Motrin accounted for one-third of Upjohn's total profits.<sup>1</sup>

Since Motrin was not a duplicate of a previously prescribed drug, Upjohn's new drug application was what is known in the industry as a "pioneer NDA." FDA generally requires an applicant for a pioneer NDA to verify the reports of clinical investigations by submitting the underlying or "raw" data upon which the investigations are based.

When a company submits a new drug application for a duplicate of a previously approved drug, the application is known as a "duplicate NDA." Although duplicate NDAs must meet the same statutory and regulatory requirements as pioneer NDAs, the FDA has adopted a policy of allowing the applicant for a duplicate NDA to rely on published scientific reports. The applicant is not required to submit the "raw" data upon which these reports are based. This policy, known as the "paper NDA" policy,<sup>2</sup> allows a manufacturer of an exact duplicate of a previously approved drug to

get approval to market the drug without performing duplicative clinical testing.

Boots submitted a new drug application which later was approved by FDA under its "paper NDA" policy. Upjohn filed a "citizen petition" with FDA pursuant to 21 C.F.R. § 10.30 and urged denial of the Boots application. Upjohn asserted that any FDA approval of the Boots paper NDA would consciously or unconsciously rely on the raw data supporting the Upjohn pioneer NDA, and that such reliance would violate FDA regulations and 21 U.S.C. § 331(j) which classify the raw data as nondisclosable trade secrets. FDA denied the Upjohn petition and approved the Boots application.

## II

In its complaint, filed in the district court, Upjohn alleged FDA could not have approved Boots' application without relying on trade secret raw data contained in the earlier Upjohn pioneer application for permission to market the same drug. Upjohn asserted that reliance on that data violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, *et seq.* and the FDA regulations promulgated thereunder. Upjohn also alleged that FDA's actions violated the Administrative Procedure Act, 5 U.S.C. § 551 *et seq.* because the actions were "unreasonable, arbitrary, capricious, an abuse of discretion, and otherwise unlawful."

Judge Gibson restricted his review of FDA's actions to the administrative record before him. That record consisted of the documents contained in the Upjohn citizen petition and the "Summary Basis of Approval"<sup>3</sup> of the Boots application.

1. New York Times, April 23, 1982, at page 32, column 6.

2. A statement of the "paper NDA" policy is published at 46 Fed.Reg. 27396 (May 19, 1981), and the reasoning underlying the policy may be found at 45 Fed.Reg. 82052-82063 (Dec. 12, 1980). The adoption by FDA of the "paper NDA" policy created considerable controversy. Allegations that the policy is illegal were rejected, however, in *Burroughs Wellcome Co. v. Schweiker*, 649 F.2d 221 (4th Cir. 1981). Up-

john opposed the "paper NDA" policy as *amicus curiae* in *Burroughs Wellcome*, but does not challenge the "paper NDA" policy in this litigation.

3. The "Summary Basis of Approval" is a summary of the data and information used to support the application, and is the essential information upon which the FDA based its approval. See 21 C.F.R. 314.14(e)(2).

Since this suit was brought pursuant to the provisions of the Administrative Procedure Act for review of a final agency action, the challenged FDA decision may be set aside only if "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A), or "unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court," 5 U.S.C. § 706(2)(F).

Upjohn argues that this is a case in which the "facts are subject to a trial de novo" and that the district court erred in restricting its review to the administrative record. Upjohn contends that, before granting the motion of defendant for summary judgment, the district court should have considered certain affidavits submitted by Upjohn. The affidavits attacked the reports and information supporting the Boots application, but were not part of the administrative record compiled by the FDA.

[1] When de novo review of agency action is not expressly required by statute, it is the exception rather than the rule. *United States v. Carlo Bianchi & Co.*, 373 U.S. 709, 715, 83 S.Ct. 1409, 1413, 10 L.Ed.2d 652 (1963) "[D]e novo review is appropriate only where there are inadequate factfinding procedures in an adjudicatory proceeding, or where judicial proceedings are brought to enforce certain administrative actions." *Camp v. Pitts*, 411 U.S. 138, 142, 93 S.Ct. 1241, 1244, 36 L.Ed.2d 106 (1973). See also *Doraiswamy v. Secretary of Labor*, 555 F.2d 832, 839-42 (D.C.Cir.1976) (collecting cases).

[2] We do not find the factfinding procedures employed by FDA in approving the Boots NDA and rejecting the Upjohn petition to be inadequate. FDA followed the applicable statutory and regulatory criteria for approving new drug applications. See 21 U.S.C. § 355(d); 21 C.F.R. § 314.1. During the two and one-half years which elapsed between the submission of the Boots application and approval by FDA of that application, FDA gathered considerable evidence with respect to the safety and effectiveness of ibuprofen. Although these factfinding procedures were informal, we do not agree with the assertion by Upjohn

that all informal factfinding procedures, no matter how complex and detailed, are inadequate in the sense that they are subject to de novo review. See *Camp v. Pitts*, *supra*, 411 U.S. at 142, 93 S.Ct. at 1244; *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 415, 91 S.Ct. 814, 823, 28 L.Ed.2d 136 (1971); *Doraiswamy v. Secretary of Labor*, *supra*, 555 F.2d 832, 840.

It is to be emphasized that Upjohn did not file with FDA the affidavits which it now contends should have been considered by the district court. Upjohn could have filed a petition for reconsideration of FDA's approval of the Boots application. 21 C.F.R. § 10.33. By that procedure the affidavits could have been submitted to FDA and made a part of the administrative record for judicial review. Instead, Upjohn chose to present the affidavits for the first time in the district court.

[3] Upjohn also argues that the district court erred in refusing to go outside the administrative record because FDA's explanation of its actions was inadequate, relying upon *Citizens to Preserve Overton Park v. Volpe*, *supra*, 401 U.S. at 420, 91 S.Ct. at 825. We do not find the explanation by the agency to be inadequate. To the contrary, FDA stated in detail the grounds for its decision and the essential facts upon which the decision was based. Nothing more is required. See *Dunlop v. Bachowski*, 421 U.S. 560, 572-74, 95 S.Ct. 1851, 1860, 44 L.Ed.2d 377 (1975).

### III

[4] Once efforts by Upjohn to supplement the administrative record were rejected, summary judgment became an appropriate manner for the district court to dispose of the controversy. *Milton v. Harris*, 616 F.2d 968, 975-76 (7th Cir. 1980); *Doraiswamy*, *supra*, 555 F.2d 832, 836; *Richards v. INS*, 554 F.2d 1173, 1177, n.28 (D.C.Cir. 1977). We agree with the district court that there is no evidence in the administrative record to support Upjohn's contentions that FDA acted arbitrarily or capriciously or abused its discretion. Moreover, we find

no evidence in the record, other than conclusory allegations by Upjohn, that FDA relied upon Upjohn's trade secret data in approving Boots' application.

#### IV

Upjohn further contends that FDA arbitrarily applied different standards in approving the Boots and Upjohn new drug applications. This is little more than an attack upon the "paper NDA" policy of FDA, although Upjohn states that it does not attack the "paper NDA" policy in these proceedings.

Boots and Upjohn were required to meet the same statutory criteria in support of their respective applications. Although there was a difference in the types of information each was required to submit, this disparity in treatment is inherent in FDA's "paper NDA" policy. Under this policy there is a difference in the position of the party submitting a pioneer new drug application and the party submitting a duplicate new drug application.

[5, 6] At the time Boots' duplicate new drug application was submitted, the FDA had acquired considerable additional information about ibuprofen through market experience which was not available at the time Upjohn filed its pioneer application. Almost all credible published reports indicate that ibuprofen is safe and effective. The record indicates that market experience with the drug supports the conclusions contained in the reports. Of course Upjohn does not contend that the drug is not safe and effective. Instead, it has mounted a technical assault on FDA's approval of the Boots application, in an effort to preserve its monopoly. The Federal Food, Drug and Cosmetic Act and the underlying regulations governing the approval for the marketing of new drugs were not intended to provide patent-like protection for a seller who has gained approval of a pioneer new drug application. It is to be emphasized that the patent to ibuprofen is owned by the parent corporation of Boots Pharmaceuticals. Upjohn has only a *non-exclusive* license from the owner of the patent to sell the drug in the Western Hemisphere.

All other contentions of Upjohn have been considered and found to be without merit. For the reasons stated above and in the comprehensive opinion of the district court, 520 F.Supp. 58, the judgment of the district court is affirmed. No costs are taxed. The parties will bear their own costs on this appeal.



James W. SUTTON, et al., Plaintiffs,

v.

George W. DUNNE, et al., Defendants.

Carl R. HANSEN, et al., Defendants-  
Cross-Plaintiffs Appellees,

v.

George W. DUNNE, et al., Defendants-  
Cross-Defendants Appellants.

No. 82-1016.

United States Court of Appeals,  
Seventh Circuit.

Argued April 6, 1982.

Decided June 10, 1982.

Rehearing and Rehearing En Banc  
Denied Oct. 5, 1982.

The United States District Court for the Northern District of Illinois, Eastern Division, Hubert L. Will, J., 529 F.Supp. 312, ordered that the board of commissioners of Cook County be increased from 15 members, nine elected from Chicago and six from the suburbs, to 17 members, ten elected from Chicago and seven from the suburbs. Defendants appealed. The Court of Appeals, Bauer, Circuit Judge, held that where apportionment plan involved only two districts, 4.22% total deviation in 1981 plan of the board was not de minimis, since the board's policy of maintaining its membership at 15 members, though board desired to save taxpayers money, was not